

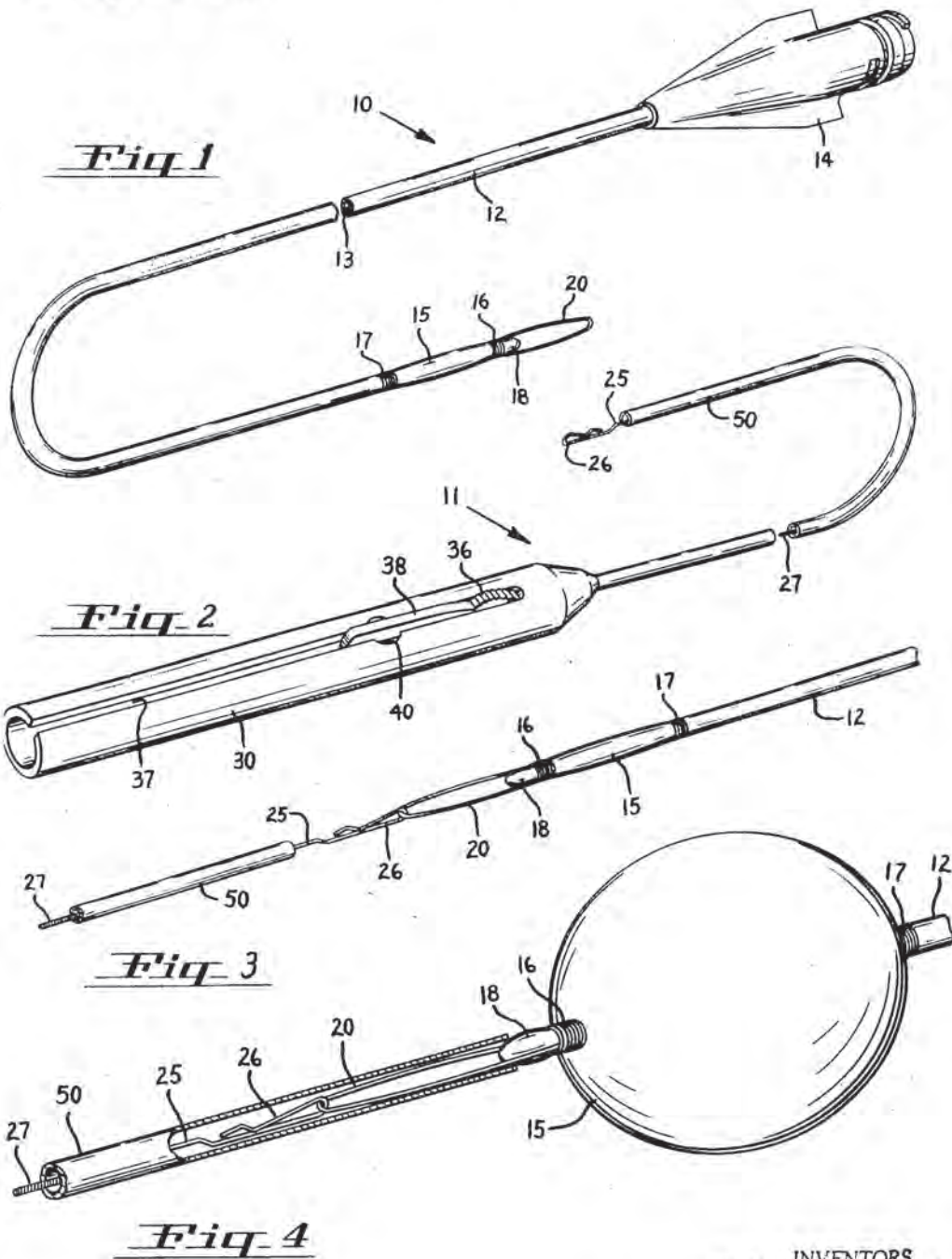
Sept. 16, 1969

T. J. FOGARTY ET AL
LEADER TYPE CATHETER

3,467,102

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2 Sheets-Sheet 1



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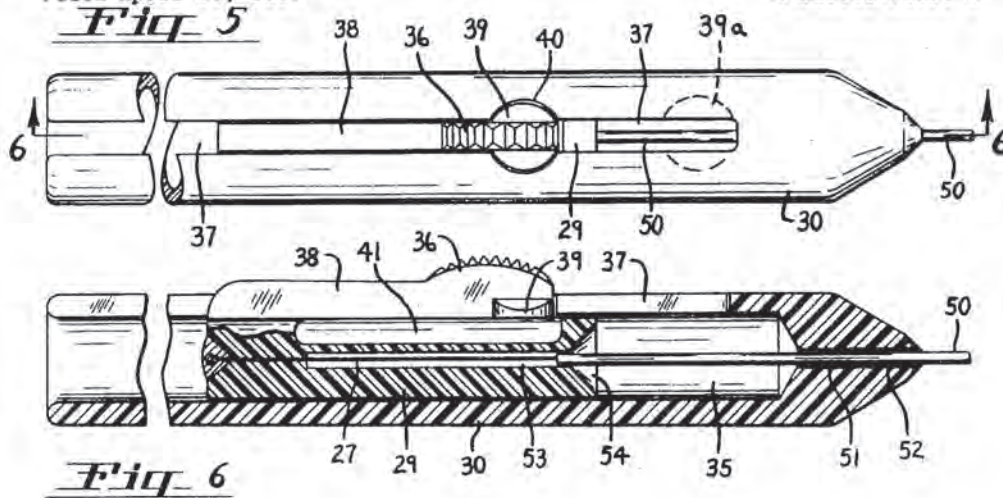
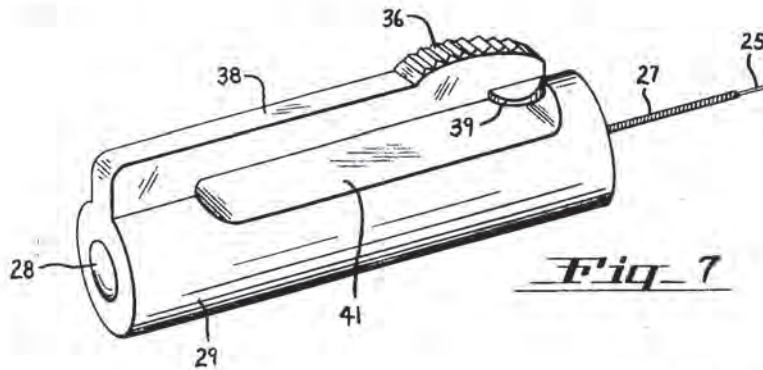
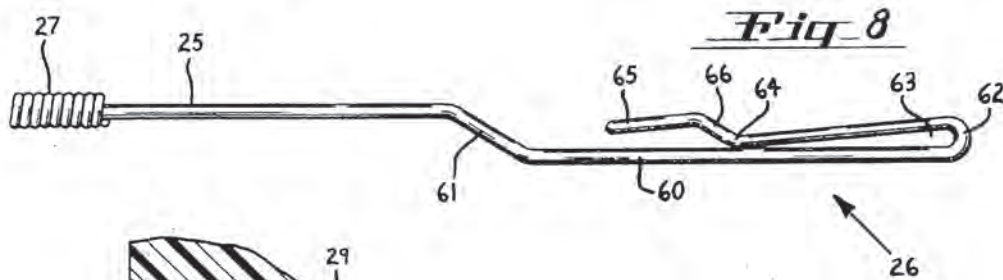
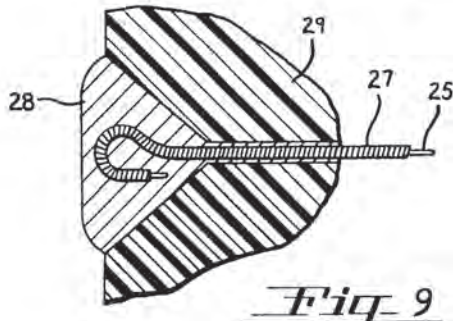
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LEADER TYPE CATHETER

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13 Claims

ABSTRACT OF THE DISCLOSURE

A catheter and leader combination for embolectomy or thrombectomy purposes and also for removal of intraductal obstructing elements. The leader is inserted through an incision in a blood vessel or other conduit on one side of an obstruction to be removed and caused to emerge from another incision on the opposite side of the obstruction. Then, by coupling the catheter to the leader, the catheter may be pulled through the obstruction with its embolectomy device in collapsed condition. The obstruction is removed by expanding the embolectomy device and pulling the catheter back out of the second incision.

BACKGROUND OF THE INVENTION

In performing an embolectomy operation with an embolectomy catheter, it is usually necessary to approach the thrombus from its proximal side, penetrate the thrombus with the embolectomy device collapsed and then expand the embolectomy device on the distal side of the thrombus so that the thrombus may be withdrawn in a proximal direction from a lumen of smaller diameter through a lumen of larger diameter. In the case of thrombus in the branching blood vessels of the lower leg, however, it is sometimes desirable to locate and enter one or more of the small vessels near the ankle in order to be sure of getting into the intended branch. Further, in the case of a venous thrombectomy, it is difficult to pass a catheter in retrograde direction, relative to the direction of blood flow, through the numerous pairs of valve leaflets in the vein. Nevertheless, it is desirable to remove the thrombus in a proximal direction for the additional reason that it is more difficult to pass the thrombus through the valve leaflets in retrograde direction. It is accordingly desirable to provide an improved thrombectomy catheter and operating technique.

SUMMARY OF THE INVENTION

Objects of the invention are to provide an improved embolectomy technique, to provide means for pulling an embolectomy catheter through a thrombus instead of pushing it through, to provide a leader for pulling a catheter through a blood vessel, and to provide a novel catheter and leader combination for any duct or lumen in the body where such device may be found useful.

The present catheter has a suture loop attached to its distal end. The leader comprises a wire with a hook on its distal end to engage the catheter loop. The leader is inserted through an incision in the blood vessel on the distal side of the thrombus, passed through the thrombus and caused to emerge from another incision on the proximal side of the proximal side of the thrombus. The catheter loop is attached to the leader hook and the catheter is pulled through the vessel with its embolectomy device collapsed until the embolectomy device has passed through the thrombus. The thrombus is removed by expanding the embolectomy device and withdrawing the catheter. By leaving the leader coupled to the catheter, multiple passes may be made.

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The invention will be better understood and additional objects and advantages will become apparent from the following description of the preferred embodiment illustrated in the accompanying drawings. Various changes may be made in the details of construction and arrangement of parts and certain features may be used without others. All such modifications within the scope of the appended claims are included in the invention. Although the invention is described particularly for use in a vein or artery by way of example, no limitation to the vascular system is intended. The present device may be used in any duct or lumen of the body where it may be found useful.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view, with parts broken away, showing the catheter portion of the device of the invention;

FIGURE 2 is a perspective view, with parts broken away, showing the leader portion of the device;

FIGURE 3 is a fragmentary view showing a first stage in the coupling of the catheter to the leader with the catheter balloon deflated;

FIGURE 4 is a similar view, with parts broken away, showing the coupling completed and the balloon inflated;

FIGURE 5 is an enlarged plan view, with parts broken away, showing the handle of the leader;

FIGURE 6 is a sectional view on the line 6—6 in FIGURE 5;

FIGURE 7 is a perspective view of the slide in the leader handle;

FIGURE 8 is an enlarged side view of the leader hook; and

FIGURE 9 is an enlarged fragmentary view of a portion of FIGURE 6.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The complete device comprises the embolectomy catheter 10 shown in FIGURE 1 and the leader 11 shown in FIGURE 2. A balloon catheter is illustrated by way of example of an expandable and collapsible embolectomy device. The catheter comprises a flexible plastic tube 12 having a lumen 13 in communication with a standard hub fitting 14 for detachable connection with a syringe or other suitable device for introducing inflating fluid for a balloon 15 on the distal end of the catheter.

Balloon 15 comprises an elastomer tube secured to the catheter tube 12 by a distal binding 16 and a proximal binding 17. The catheter tube is apertured between these two bindings to communicate fluid pressure from lumen 13 to the balloon. Distal binding 16 is spaced a short distance from the catheter tip 18. The ends of a loop 20 of suture material are secured under the distal binding 16.

Leader 11 comprises a flexible wire 25 having a hook 26 on its distal end. For the purposes of flexibility and strength, wire 25 is preferably a relatively fine music wire. Wire 25, except for its distal end portion, is enclosed in a sheath formed by a tight coil 27 of fine music wire as shown in FIGURE 8. The proximal ends of wire 25 and coil 27 are anchored to a button 28 as shown in FIGURE 9. Button 28 is secured in the rearward end of a slide 29 in a tubular handle 30 as shown in FIGURE 6. Slide 29 is movable longitudinally in a bore 35 in handle 30 and is equipped with a thumb latch 36 disposed in a longitudinal slot 37 in the handle body.

Latch 36 comprises the end portion of a resilient arm 38 on the slide 29 whereby the latch may be pressed down by the thumb and the resilience of the material will cause the latch to spring back when pressure is released. Latch 36 includes a circular button detent 39 which is received in a circular enlargement 40 of the slot 37 to

lock the slide in its rearward position as shown in FIGURES 5 and 6. By depressing the latch 36, the button 39 may be pressed down into a recess 41 in the slide 29 so that the slide may be moved forward in the handle. The slide is shown in its forward position in FIGURE 2 and the forward position of button 39 is indicated at 39a in FIGURE 5.

Wire 25 and coil 27 slide within a flexible plastic guide tube 50. A proximal end portion of tube 50 is secured in a bore 51 in the forward end of handle 30 by means of cement 52. The end of tube 50 extends loosely into a bore 53 in the slide 29. To facilitate assembly of the parts, the forward end of bore 53 is enlarged in funnel shape as indicated at 54 in FIGURE 6.

Hook 26 has a straight shank portion 60 which is offset at 61 to one side of the axis of wire 25 and parallel thereto as shown in FIGURE 8. The wire has a reverse bend at 62 forming a loop or eye 63 which is closed by a lip portion 64 that bears against shank 60. To facilitate engaging the suture loop 20 in the hook, the end 65 of the lip is offset at 66 from the portion 64 so that end 65 will remain spaced a short distance away from shank 60. Offset portion 66 slopes toward the eye 63 so that when suture loop 20 is engaged behind lip end 65 and pulled toward the bend 62, the loop will pass readily under the portion 64 and enter the eye. Once in the eye 63, the loop 20 is retained therein by the spring pressure of portion 64 bearing against shank 60 so that the loop cannot accidentally become disengaged from the hook.

The widest portions of the hook 62 and 66 are narrower than the offset at 61 whereby the hook may be freely drawn into tube 50 without lip end 65 catching on the end of the tube. Also, to guide the hook in to the tube, the offset 61 is disposed at an oblique angle and lip end 65 converges slightly toward shank portion 60.

When latch 36 and slide 29 are pushed forward as shown in FIGURE 2, hook 26 is projected out of the end of tube 50. Whereas the wire 25 is so fine it would assume a sinuous configuration within tube 50 and could not be pushed freely through the tube by itself, the coil 27, the adjacent turns of which are in contact with each other, forms a compression member which can be pushed freely through the tube against sliding friction so that hook 26 will move forward the same distance that slide 29 is moved forward. At the same time, coil 27 is so flexible that it does not objectionably stiffen the leader assembly comprising wire 25, coil 27 and tube 50. This leader assembly must be freely bendable. When latch 36 is retracted in slot 37 to its position shown in FIGURES 5 and 6, hook 26 is drawn into the end of tube 50 and button 39 snaps into enlarged opening 40 to lock the slide 29 in retracted position.

By way of example, the operation of the instrument will be described in connection with the removal of thrombus from an artery of the lower leg. First, the femoral artery is prepared for insertion of the catheter 10 at some point in the patient's thigh. Next, the surgeon locates the anterior tibial, posterior tibial or peroneal artery, or any desired combination thereof, in the vicinity of the ankle and prepares the selected vessel or vessels for insertion of the leader 11. With hook 26 retracted, the distal end of leader tube 50 is then introduced and passed in retrograde direction in the vessel until the distal end appears at the prepared incision in the femoral artery. The end of tube 50 is projected a short distance through the incision in the femoral artery and hook 26 is extended as shown in FIGURE 2.

Catheter loop 20 is engaged with hook 26 as shown in FIGURE 3 and then the hook is retracted into the tube as shown in FIGURE 4, except that balloon 15 is not inflated at this time. The length of suture loop 20 is such as to pull the catheter tip 18 up against, or partially into, the end of tube 50 as shown when slide 29 has been retracted to the point where button 39 snaps into opening 40. The leader 11 is then employed to draw the

catheter with deflated balloon into the small lumen distal end of the selected vessel, the leader guiding the catheter tip from the femoral artery into the selected vessel in the ankle.

When the catheter tip has been drawn beyond the thrombus, the balloon is inflated and the thrombotic material is withdrawn from the vessel in retrograde direction by pulling the catheter out of the femoral artery incision. By leaving the catheter and leader coupled together, multiple passes may be made.

An additional advantage of the leader will be readily apparent in a case of thrombus in a vein in the lower leg. The leader tube 50 will pass relatively freely in a proximal direction through the valve leaflets in the veins. When the leader has made its passage, and has been connected with the catheter as above described, the catheter, by reason of its close coupling with the leader, may be pulled downward in retrograde or distal direction through the valve leaflets with the balloon deflated. Then the catheter with its balloon inflated is pulled back in a proximal direction causing the balloon to push the thrombus through the valve leaflets and through the widening lumen in the direction of the venous blood flow for removal through an incision in the large femoral vein in the thigh.

Having now described our invention and in what manner the same may be used, what we claim as new and desire to protect by Letters Patent is:

1. A leader and catheter including a leader comprising an elongated flexible member adapted to be pushed in one direction through a body lumen such as a blood vessel, a catheter, and means to couple the distal end of said leader with the distal end of said catheter for pulling the catheter through the lumen in trailing relation to the leader when the leader is withdrawn from the lumen in the opposite direction.

2. A leader and catheter as defined in claim 1, said coupling means comprising a hook on said leader and a loop on said catheter.

3. A leader and catheter as defined in claim 2, said catheter having a balloon secured by a binding on the catheter, said loop comprising a strand of suture material secured under said binding.

4. A leader and catheter as defined in claim 1, said leader comprising a wire in a flexible tube, one element of said coupling means being on said wire, and means to extend said wire from the distal end of said tube for connecting said coupling means together and to retract said wire to pull said coupling means substantially into said tube.

5. A leader and catheter as defined in claim 4, including a handle on said leader fixedly connected to said tube, said extending and retracting means comprising a slide in said handle connected with said wire, and means to lock said slide in retracted position.

6. A leader and catheter as defined in claim 5, said one element of said coupling means on said leader comprising a hook on said wire, said hook being shaped to slide freely into said tube.

7. A leader and catheter as defined in claim 4, said wire being covered by a flexible sheath.

8. A leader and catheter as defined in claim 7, said flexible sheath comprising a wire coil.

9. A catheter comprising a catheter tube, a balloon concentric with said tube, proximal and distal bindings securing the ends of said balloon on said tube, and a loop for pulling the catheter through a body lumen, said loop comprising a strand of suture material having portions thereof secured under said distal binding.

10. A catheter leader comprising a handle, a flexible tube secured at its proximal end to said handle, a wire slidable in said tube, catheter coupling means on the distal end of said wire, and means in said handle for sliding said wire to project said coupling means out of the distal

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end of said tube and retract said coupling means into said tube.

11. A catheter leader as defined in claim 10, said coupling means comprising a hook on said wire having an offset shank and a spring lip portion bearing against said shank to form a closed eye, said shank and lip portions being of less width than the offset of said shank so that said hook will slide freely into the end of said tube.

12. A catheter leader as defined in claim 10 including a thrust member on said wire, said thrust member comprising a second wire coiled around said first wire.

13. A catheter leader as defined in claim 10, said means for sliding said wire comprising a slide in said handle, a bore in said slide slidably receiving said tube,

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means in said slide anchoring the proximal end of said wire, and means for locking said slide in retracted position.

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L. W. TRAPP, Primary Examiner